N/A
Maryland Board of Pharmacy
Public Meeting
Minutes

Date: August 17, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner		X	1	1
Chason, D.	Commissioner			2	0
Finke, H.	Commissioner			2	0
Gavgani, M. Z.	Commissioner			1	1
Handelman, M.	Commissioner			2	0
Israbian-Jamgochian, L.	Commissioner/Treasurer			2	0
Matens, R.	Commissioner			1	1
Souranis, M.	Commissioner//President			2	0
St. Cyr, II, Z. W.	Commissioner			2	0
Taylor, D.	Commissioner			2	0
Taylor, R.	Commissioner/Secretary			1	1
Zimmer, R.	Commissioner			2	0
Bethman, L.	Board Counsel			2	0
Felter, B.	Assistant Board Counsel			2	0
Naesea, L.	Executive Director			2	0
Wu, Y.	Compliance Manager			1	1
Daniels, D	Licensing Manager			2	0
Gaither, P.	Administration and Public Support Manager		X	1	1
Seeds, J.	Public Information Officer/Secretary			2	0
Jeffers, A.	Legislation/Regulations Manager			2	0

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Board Action
I. Executive Committee Report(s)	**M. Souranis, Board President**	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.*		
		1. Call to Order	1. N/A	**1. Mike Souranis called the Public Meeting to order at 9:46 A.M.**
		2. Sign-in Introduction and of meeting attendees – *(Please indicate on sign-in sheet if you are requesting CE Units for attendance)*	2. N/A	**2. No action required.**

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		Mike Souranis requested all meeting attendees to introduce themselves and to sign the guest list before leaving the meeting.		
		3. Distribution of packet materials – M. Souranis reported that guests will be given packets of materials so that they can follow meeting discussions. He requested that all guests return the draft packets before leaving the meeting.	3. Materials to be collected at conclusion of Public Meeting.	**3. No action required**
	R. Taylor Secretary	**4. Review & Approval of Minutes of June 15, 2011** Minutes had not been posted so will be reviewed and approved later in this meeting.	4. To be approved on later date. .	**4. No action.**
II. Staff Operations Report (s)	**A. L. Naesea,**	**1. Operations Updates** – L. Naesea reported that freeze exemptions had been granted for all vacant positions. Recruitment for interviews is in progress.	1. Update Only (L. Naesea/P. Gaither)	**1. No Board action Required.**
		2. Meeting Updates - Secretary Sharfstein directed Senator Hollinger to meet with Board Directors to discuss Scope of Practice issues. Sen. Hollinger explained that the Secretary is considering introducing legislation to convene an independent panel to review scope of practice disputes between two HO Boards and provide recommendations.	2. Meeting Updates (L. Naesea)	**2. No Board action required.**
B. Administration and Public Support	**A.L. Naesea for B. P. Gaither, Manager**	**1. Personnel Updates: Vacancies and Recruits – See above.**	1. N/A	**No Board action required.**
		2. Contracts and Procurement – The contract for MIS project management was issued with closing date on September 9, 2011.	2. Update (l.Naesea/P.Gaither)	
C. MIS	**L. Naesea**	**Database Implementation Project -** The Systems Automation project timeline has been revised with a "rollout" date for testing moved from October 1, 2011 to Nov. 3, 2011. This will allow for adequate testing of the pharmacy renewal system.	Update (L.Naesea/M.Hsu)	**No Board action required.**
D. Licensing	**D. Daniels, Manager**	**Licensing Unit Update:** Monthly Statistics for the end of the month of July were provided. The total pharmacists are 8784	Update (D.Daniels)	**No Board Action required.**

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		(115 new, 354 renewed, 358 non-renewed). The total technicians are 8026. Current pharmacies are 1766 (12 new, 4 repositories, 2 drop-off). Current distributors are 780 (9 new).		
E. Compliance	**Y. Wu, Manager**	**1. Inspection Program Report -** Statistics for the end of July were provided. Ninety (90) Inspections were conducted. **2. PEAC Update-** Tony Tommasello of PEAC indicated that they are tracking 20 cases (19 pharmacists and 1 technician). 52 drug test results were received in the month of July with no positives.	1. Update (Y.Wu) 2. Update (S.Kreindler)	**1. No Board Action required.** **2. No Board Action required.**
F. Legislation & Regulations	**A. Jeffers**	***1. Status of Proposed Regulations*** ***a. 10.34.03 Inpatient Institutional Pharmacy*** *Notice of Final Action to be published on September 9, 2011 with Effective Date of October 1, 2011.* ***b. 10.34.14 Opening and Closing of Pharmacies*** *Referred to August 24, 2011 Practice Committee* ***c. 10.34.25 Delivery of Prescriptions*** *Proposal and documentation submitted July 28, 2011.* ***d. 10.34.28 Automated Medication Systems*** *Informal Comments concerning the June 21, 2011 version of COMAR 10.34.28:* *Bruce Krug - Release of revisions to COMAR 10.34.28 Auto Med Syst*	a. The proposed effective date for the regulations is October 1, 2011. (A. Jeffers) b. Update c. Update d. Board approval requested for responses to informal comments	**a. No Board Action Required.** **b. No Board Action Required.** **c. No Board Action Required.** **d. Board approved.**

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		Bd Response - Informal Comment July 2011 - 10.34.28 – Omnicare Thank you for submitting Omnicare's informal comment to the Maryland Board of Pharmacy (the "Board") concerning the June 21, 2011 released revisions to Code of Maryland Regulations (COMAR) 10.34.28 Automated Medication Systems. Below you will find the Board's responses to your concerns. 1) You had noted that while the regulation clearly details the requirements for the three major types of system (decentralized, remote and centralized), they actually define only two of these (remote and decentralized) in the definitions section, but not the third (centralized). The definition for "Centralized automated medication system" remains unchanged from the existing COMAR text for 10.34.28.02B(2) and it is indicated on the June 21, 2011 released version as "(text unchanged)." In the existing text it is defined: (2) "Centralized automated medication system" means an automated medication system located in a pharmacy from which medication is distributed or prepared for final dispensing by a licensed pharmacist for a specific patient. 2) You had also noted that Section .04 Usage Requirements for Centralized Automated Medication Systems, appeared to discuss the remote and decentralized systems more than it did the centralized system. In the June 21, 2011 released version of revisions to COMAR 10.34.28, deleted text is enclosed in brackets. If you remove the sections enclosed in brackets it will show references to remote and decentralized systems will be removed.		

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		The Board would like to thank you again for your thorough reading of, and informal comments to, the recently released revisions to COMAR 10.34.28 Automated Medication Systems. The Board considered Omnicare's informal comments at the August 17, 2011 Board Meeting and voted to propose again COMAR 10.34.28 to reflect the June 21, 2011 version released for informal comment. **MD BOP automated medication systems_informal comments_Kaise 072111** **Bd Response - Informal Comment July 2011 - 10.34.28 – Kaiser Permanente** Thank you for submitting Kaiser Permanente's informal comment to the Maryland Board of Pharmacy (the "Board") concerning the June 21, 2011 released revisions to Code of Maryland Regulations (COMAR) 10.34.28 Automated Medication Systems. The Board has worked diligently with stakeholders such as Kaiser Permanente to craft regulations that reflect the existing, and ever changing, use of automated medication systems. The Board is pleased that the June 21, 2011 version of the proposed revisions is acceptable to Kaiser Permanente. The Board will not be making any further revisions before submission for publication. The Board would like to thank you again for your thorough reading of, and informal comments to, the recently released revisions to COMAR 10.34.28 Automated Medication Systems. The Board considered Kaiser Permanente's informal comments at the August 17, 2011 Board Meeting and voted to propose again COMAR 10.34.28 to reflect the June 21, 2011 version released for informal comment. **Board approval requested to submit the June 21, 2011**		

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		version of COMAR 10.34.28 into the regulatory process. Anna Jeffers presented a history of the promulgation of these regulations since the law passed in 2008. An initial Board Member Committee of Dave Chason, Cindy Anderson, and Harry Finke drafted the original version. The proposed revisions were released for informal comment on October 2008. The proposal was revised between November and March 2009. The Board approved the proposal on April 15, 2009 and then again on May 20, 2009. Two informal comment periods followed and the Board approved the proposal again in August and September 2009. The proposal was published in the Maryland Register on December 4, 2009. Comments were received and revisions were voted on at the February, March and July 2010 Board Meetings. A re-proposal was published January 14, 2011. One comment was received and the Board approved proposing the regulations anew. Revisions were made and the proposal was released for informal comment again on June 21, 2011. Discussion ensued and concerns were expressed that the remote automated medication systems were not required to be patient specific. Additionally it was noted that the proposed regulations may not be appropriate for comprehensive care facilities.		

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		It was explained that the statute, Health Occupations Article, 12-605, does not require that remote automated medication systems be patient specific. The Board voted to approve the proposed regulations to be promulgated anew. **Release of Proposed COMAR 10.34.28 Auto Med Systems 061511** **e. 10.34.32 Pharmacist Administration of Vaccinations** (to be promulgated in consultation with the Department pursuant to SB 845) Board approval requested for the Practice recommendation to revise the draft regulations with 3 requirements when administering to individuals 9 years and older: 1) Provide the patient with the VIS from; 2) Obtain a signed consent form; and 3) "The pharmacist should observe the patient for a period of time after administration of the vaccine." Submitted to the Department for review June 23, 2011. NORD submitted July 7, 2011. Received approval from the Department on August 3, 2011. The Board voted to approve the proposed regulations to be submitted on an Emergency basis so that the effective date of the regulations would coincide with the effective date of the statute.	e. N/A f. N/A	**e. No Board Action Required.**

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		f. 10.34.32 Pharmacist Administration of Vaccinations – inclusion of travel vacines – meeting scheduled with Bd of Nursing and Bd of Physicians for August 31, 2011.	(A Jeffers)	**f. No Board Action Required.**
		g. 10.34.33 Prescription Drug Repository Programs A Board Subcommittee is continuing to work on wording and waiting for the promulgation of the federal regulations this summer. Meeting scheduled with the Attorney General's Office for September 28, 2011.	g. N/A (A Jeffers)	**g. No Board Action Required.**
		h. 10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment Published August 12, 2011 with comment period through September 12, 2011.	h. N/A (A Jeffers)	**h. No Board Action Required.**
		i. 10.13.01 Dispensing of Prescription Drugs by a Licensee -A meeting was held with representatives from the stakeholder Boards per direction from Wendy Kronmiller on September 30, 2010. -DDC PIA request for Inspection Reports – DDC requested an extension until -December 17th – Received December 16, 2010. -Legislation was introduced, but did not pass. -The Senate Education, Health and Environmental Affairs Committee, Health -Subcommittee will meet in June to determine the summer schedule to assist the Boards in resolving the dispensing of prescription drugs by	i. N/A (A Jeffers)	**i. No Board Action Required.**

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		licensees. -Sara Fidler, Counsel for EHE, indicated that Senator Joan Carter Conway wanted the Boards to meet with Sara Fidle and let her know what cannot be resolved. -Email sent to parties the first week of August Meeting scheduled for October 12, 2011.		
		j. 10.44.30 Board of Dental Examiners - Record Keeping Comments **sent July 27, 2011.**	j. N/A (A Jeffers)	**j. No Board Action Required.**
		k. 10.19.03.13 Controlled Dangerous Substances, Additional Controlled Dangerous Substances – Schedule I. Board approval requested for comment concerning the proposed COMAR 10.19.03.13	k. N/A (A Jeffers)	**k. No Board Action Required.**
		l. 10.19.03.13 Proposed to_12290_1	l. N/A (A Keffers	**l. No Board Action Required.**
		Board of Pharmacy comment COMAR 10.19.03.13 Dear Ms. Phinney: The Maryland Board of Pharmacy thanks the Department of Health and Mental Hygiene for giving the Board the opportunity to comment on the proposed COMAR 10.19.03.13 Controlled Dangerous Substances, Additional Controlled Dangerous Substances – Schedule I. The Board strongly agrees with the proposed inclusion of 3,4 – Methylenedioxypyrovalerone (MDPV);, 4 – Methylmethcathinone (Mephedrone, 4-MMC), 3,4 – Methylenedioxymethcathinone (Methylone, MDMC), 4 – Fluoromethcathinone (Flephedrone, 4-FMC), 3 –	N/A (A Jeffers)	**No Board Action Required.**

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		Fluoromethcathinone (3-FMC), and 4 – Methoxymethcathinone (Methedrone, bk-PMMA, PMMC) - generically known as "bath salts," in Maryland's list of Schedule I controlled dangerous substances. The Board, however; recommends that the proposal be expanded to include the entire list of drugs listed in Federal Legislation S.B.605/H.B.1254 Dangerous Synthetic Drug Control Act of 2011. The entire list of substances follows: • 4-methylmethcathinone (Mephedrone) • 3,4-methylenedioxypyrovalerone (MDPV) • 3,4-methylenedioxymethcathinone (methylone) • Naphthylpyrovalerone (naphyrone) • 4-fluoromethcathinone (flephedrone) • 4-methoxymethcathinone (methedrone; Bk-PMMA) • Ethcathinone • 3,4-methylenedioxyethcathinone (ethylone) • Beta-keto-N-methyl-3,4-benzodioxyolybutanamine (butylone) • N,N-dimethylcathinone (metamfepramone) • Alpha-pyrrolidinopropiophenone (alpha-PPP) • 4-methoxy-alpha-pyrrolidinopropiophenone (MOPPP) • 3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (MDPPP) • Alpha-pyrrolidinovalerophenone (alpha-PVP) • 6,7-dihydro-5H-indeno(5,6-d)-1,3-dioxal-6-amine (MDAI) The inclusion of the above substances would further protect the public in Maryland by restricting all access to these substances by the public. In the interest of public protection, the Board hopes that the Department will give the inclusion of these additional substances full consideration. Should you have questions, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.	m. N/A	

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		m. 10.09.03 Medical Care Programs – Pharmacy Services This proposal was published on July 29, 2011 and any Board comment is due by August 29, 2011. It was recommended that the Board submit a comment expressing concern that there may be harm to patients if the fee is reduced to zero for compounding IV medications unless filling for a nursing home patient. The comment will be finalized at the August 24, 2011 Practice Committee Meeting. **n. 10.25.16 MHCC – Electronic Health Record Incentives** This proposal was published on July 29, 2011 and any Board comment is due by August 29, 2011. The Board did not recommend submitting a comment. **2. Task Force on Regulatory Efficiency Interim Report** **Any comments? FYI** **Task Force on Regulatory Efficiency Interim Report, Final, July 27, 2011**	(A Jeffers) n. N/A (A Jeffers)	**m. No Board Action Required.** **n. No Board Action Required**
III. Committee Reports **A. Practice Committee**	**H. Finke, Chair,**	**Letters for Board Approval** **1. Bryan Hayes, PharmD, Clinical Specialist, Emergency Medicine & Toxicology University of Maryland Medical Center** **Administration of emergency IV meds by pharmacists** **Draft Bd Response - Admin of IV meds by pharmacists** Thank you for contacting the Maryland Board of Pharmacy regarding whether the board has ever looked into pharmacists administering IV medications in emergent situations (e.g.,	1. Letter was amended to take out the word 'emergency.' Without this being changed, it seems to be outside their scope of practice.	**1. Practice Committee recommended approval of letter as amended.** **Seconded: Reid** **Zimmer**

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		cardiac arrests). Administering IV medications in any situation is outside the scope of practice for Maryland pharmacists.		
	D. Chason Chair,	**1. Review of Pharmacist Applications:** • **Yang, Jenny -** Applicant requested that the live CE requirement be waived. Applicant was notified that the CE requirement was not met and responded the she had not read the Board notices and was preoccupied with a seriously ill child. Recommendation is to approve waiver of reinstatement fee but not live CEs	• After discussing, it was suggested that the reinstatement fee be waived, but not the CEs.	• **The Licensing Committee moved to approve the waiver of the reinstatement fee. The CE requirement is to remain.** **Seconded: Reid Zimmer** **The motion carried.**
		• **Kale, Amit -** Applicant is a foreign graduate who has passed the FPGEC and is requesting waiver of the 150 hours of practical experience. Is requesting to substitute time worked in the pharmaceutical industry. Recommend denial of request.	• 1500 hours of practical experience is required .	• **The Licensing Committee moved to deny the request.** **Seconded: Harry Finke** **The motion carried.**
		• **Newman, David** - Applicant submitted a reinstatement application on 03/26/2010. Applicant has completed the exam requirements on 07/09/2011. Application expired 03/26/2011. Applicant is requesting waiver of the $540.00 reactivation fee due to not receiving the law several months after applying for the reinstatement. Recommend denial of request.	• It is the responsibility of the applicant to know the requirements for reinstatement.	• **The Licensing Committee moved to deny the request.** **Seconded: Reid Zimmer** **The motion carried.**
		• **Kim, John -** Pharmacist is requesting waiver of reinstating its license and submitting a regular renewal application due to having constant problems renewing online. Applicant tried notifying Michelle to fix problem on 08/01/2011 but she was on vacation. Recommend denial of request.	• After discussing, it was determined that the law states that applications are to be submitted 14 days before expiration.	• **The Licensing Committee moved to deny to request.** **Seconded: Richard Matens**

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				The motion carried.
		2. Review of Pharmacy Applications: • **Invictus Healthcare Solutions, LLC -** Applicant is requesting approval as a waiver pharmacy providing services to assisted living facilities, and veterinary hospitals as well as performing non-sterile compounding. OK for waiver, recommendation is to approve.	• R. Taylor suggested that the company provide a business plan to demonstrate expertise in each area or proposed specialty.	• **The Board moved to refer the application back to the Licensing Committee for further review based on the new regulations of more than one criteria. Seconded: Mayer Handelman** **The motion carried.**
		3. Review of Distributor Applications: • **KCI USA -** Applicant questioned the requirement to be licensed in Maryland as a distributor because the product, VAC, is a device not sold by pharmacies. Recommendation is to approve.	• The device is used in skin repair and is covered.	• **The Licensing Committee moved to approve KCI USA to use the VAC. Seconded: Mayer Handelman** **Board approved KCI as a distributor.**
		• **Rouses and Akrimax** – The NABP inspector hired as the Board's agent reported that the two companies are located in the same building on the same floor. They are managed by separate executive staff and boards but share finance and other administrative functions. Recommendation is to approve.	• After discussing, it was decided that it was okay for the two companies to share some resources because they have differing governing Boards and have separate permits.	• **The Licensing Committee moved to approve this as they are separate entities. Seconded: Reid Zimmer** **The motion carried.**
		4. Review of Repository/Drop Off Site Applications: • Discussion regarding how donated drugs may be dispos. It was decided that a letter needs to be drafted to each applicant addressing questions of 1) where and how discarded drug deposits may be destroyed, and 2) requesting plan for disposal of drugs planned for	• Drugs cannot be destroyed	• **No action required.**

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		disposal. **5. Review of Pharmacy Technicians Training Programs:** • **City Pharmacy of Elkton -** has been assigned to Mitra Gavgani for review.	• Mitra has been assigned to review pharmacy.	• **No action required.**
C. Public Relations Committee	**L. Bradley-Baker Chair**	**1. Newsletter -** . J. Seeds reported that copies of the newsletter are planned for mailing in early September.. **2. Annual Report -** The template for the FY11 Annual Report (July 1, 2010 through June 30, 2011) has been completed and is ready for reports to be inserted. The Board projects printing the report by the end of 2011. 3. **CE Breakfast –** Letters have been drafted inviting presenters for the event**.** The presenters resumes and course contents will be sent for ACPE assessment in order to determine allowable CE credits.	1. The due date for articles for the Fall 2011 newsletter is the 18th of August. The newsletter is scheduled to be submitted to the printer on or about August 25th . (P. Gaither/J.Seeds) 2. NA (P. Gaither/J.Seeds) 3 .N.A (P. Gaither/J.Seeds)	**1. No action required.** **2. No action required.** **3. No action required.**
D. Disciplinary	**L. Israbian-Jamgochian Chair**	**Committee Updates**.	No report given.	**No action required.**
E. Emergency Preparedness Task Force	**D. Taylor Chair**	**Task Force Updates:** D. Taylor reported that the State received scores for its participation in the last CDC emergency preparedness exercises. The EP pharmacist team scored 97. The entire pharmacy contingency scored 100.	N/A (P. Gaither/J.Seeds)	**No action required.**
F. Drug Therapy Management	**Rodney Taylor Co-Board Representat.**	**1. Fink's Pharmacy** – Metabolic Syndrome (renewal application submitted with changes) – The Board of Physicians did not approve this protocol because it did not agree with the applicant's plan to allow physicians to be located off- site from the pharmacy. The Board of Physicians has invited the applicant to meet with the Board at a public Board meeting .	1. The Board of Pharmacy representatives n the Joint Committee recommend approval of the application.	**1. DTM Joint Committee representatives moved to approve Finks Pharmacy application.** **Seconded: Dave Chason** **The motin was carried.**

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		2. Letter Sent to Sec. Sharfstein – L. Naesea prepared and sent a DTM letter to Secretary Sharfstein to request support in resolving the current issue with the Physician Board requiring the restriction of the substitution of chemically dissimilar drugs in protocols that are allowed by the DTM statute and regulations. Ratification by Board required.	2. L. Naesea recommended that the Board vote to ratify the DTM Letter sent to Secretary Sharfstein.	**2. The Board approved ratification of the letter.**
IV. Other Business & FYI	**M. Souranis**	**CMS Rule on Pain Medications for Infusion Pumps – added** –The proposed rule would allow sterile compounding in physicians' offices, and contradict some requirement of USP 797. Board members felt that formal comment should be submitted: addressing: the importance of knowing who would be qualified to compound meds in a physician's office; noting that USP 797 requires specific facilities to be used to compound medications; pointing out staff training needs; the need for a pharmacist check requirement; the fact that that pumps are only filled every 3 months so they must be compounded in sterile sites; and other discussed concerns. M. Gavgani explained the compounding process to Board members.	1. Practice Committee to prepare the letter for sending in early September. (A. Jeffers)	**1.** M. Gavagani moved that comments be formally submitted. **to CMS and copied to NABP, USP, HSS, and congress members.** **Seconded: D. Chason** **The Motion was carried.**
V. Adjournment	**M. Souranis, Board President**	**The Public Meeting was adjourned at 11:37 AM.** **At 11:47 A.M. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.** **C. The Closed Public Session was adjourned at 11:45 A.M. ? Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.**	N/A	**Mike made a motion that public meeting be adjourned. Seconded: Reid Zimmer**